UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,888	06/08/2001	Anders Pettersson	103364702US	9971

466 7590 09/26/2002

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,888	PETTERSSON ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 1 and 20 are objected to because of the following informalities: in the last line of claim 1, there is a space between the word "surface" and its "s", and in claim 20 the word method is misspelled as "metod". Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1 – 21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 – 17, 19 and 20 of copending Application No. 09/787,887. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '887 Application claims could read as prior art over the current application.

Claims 1 – 18 of the instant case are drawn to a pharmaceutical composition for the treatment of acute disorders, sublingually with fentanyl or an acceptable salt. The composition is

an ordered mixture of micro-particles that is free of water. The composition comprises carrier particles, which are coated to the surface of smaller active agent particles. The carrier comprises disintegrants, surfactants and other commonly used excipients all well known in the art. Claims 19 – 21 are drawn to a method of treating an acute disorder using the composition of the invention.

Claims 1 – 17 of the '887 application are drawn to pharmaceutical composition for the sublingual treatment of acute pain, sublingual with fentanyl. The composition is an ordered mixture of micro-particles what is free of water. The composition comprises carrier particles, which are coated to the surface of smaller active agent particles. The carrier comprises disintegrants, surfactants and other commonly used in the art. The claims differ in that the compound is used for the treatment of acute pain instead of an acute disorder. Claims 19 and 20 are drawn to method of treating acute pain using the composition of the invention.

Despite their differences one of ordinary skill in the art would be motivated to use the composition of current application to treat acute pain, which is in essence an acute disorder. The compositions of the two applications are identical. The compositions share the same active agent, the same carrier constituency, the same particle size and active agent dosage. It would have been obvious to a skilled artisan to use either the composition of the present invention or that of the '887 application to deliver a therapeutic effect.

Accordingly the claimed composition and method in the copending application and the present application are obvious over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nyström (EP 0 324 725) in view of knowledge in the art. Claims 1 – 18 are drawn to a pharmaceutical composition for the treatment of disorders, sublingually. The composition is an ordered mixture of micro-particles that is free of water. The composition comprises carrier particles, which are coated to the surface of smaller active agent particles. The carrier comprises disintegrants, surfactants and other commonly used excipients all well known in the art. Claims 19 – 21 are drawn to a method of treating a disorder sublingually using the composition of the invention.

Nyström teaches essential elements of the claimed invention. The reference discloses an ordered mixture of drug particles in a carrier composition. The compound of the invention is water-free and includes comprises conventional pharmaceutical additives such as glidants,

lubricants, surfactants, disintegrants, and other compounds well known in the art. The drug particles of the invention measure no larger than 10 microns, while the carrier particles measure between 100 and 500 microns. The active agent is selected from various analgesic or anesthetic compounds known in the art, yet the specific compound is only restricted by its solubility in water, the lower the better. The most important aspect of the invention is the fact that the compound remains water-free so that the active agents do not dissolve too quickly. Also Nyström teaches various delivery methods, including oral and topical. The delivery method and specific location is non-critical as long as the composition remains water free (col. 2, lin. 43 – col. 5, lin. 14; Examples).

Though the reference discloses many essential elements of the claimed invention, it is silent to particular active agent, the specific constituents of the carrier compound. The reference teaches that microcrystalline cellulose, polyvinylpyrrolidone and mannitol (Examples), but a specific surfactant is not named, though lubricants are suggested as additives. Nyström further differs in that it does not use the same active agent in its compound. The reference discloses various analgesic compounds that can be used, and stipulates that though these are not a complete list, any compound can be incorporated in to the composition depending upon its water solubility.

With regard to the active agent as claimed by applicant, fentanyl is well known in the art as an analgesic. As disclosed by Fine et al (Clinical Note, *Pain*, **45**, 1991, 149 – 153) oral transmucosal fentanyl citrate (OTFC) has been used in the art to deliver the analgesic sublingually. In the form of lollipops and lozenges, the OTFC has been delivered to patients suffering from acute breakthrough pain (Introduction).

With regard to the constituents of the present invention, specifically the carrier particles, these are also well known in the art. Nyström clearly names the bio/mucoadhesive (microcrystalline cellulose), the disintegrant (polyvinylpyrrolidone) and the carbohydrate (mannitol) of the current invention, yet only suggests the use of a surfactant. The reference suggests that other excipients known in the art be uses, such as lubricants, of which surfactants can be used. As seen in many of the Stanley patents for the sublingual administration of analgesics, specifically USPN 5,288,498, sodium lauryl sulfate is used as the surfactant to lubricate the composition, which delivers fentanyl (Abstract, Examples).

With regard to claims 19 – 21 which recite a method for treating acute disorders using the composition of the invention. Though Nyström does not suggest the therapeutic effects of the composition, it is apparent that with the addition of analgesic or anesthetic compounds, the composition given its constituency and dissolution profile could be used to treat a range of disorders. Coupled with the knowledge in the art of OTFC, a skilled artisan would be able to use the invention of Nyström to deliver therapeutic agents to treat disorders acute or otherwise.

With regard to claims 5, 9 and 21, which recite specific concentrations and dosages for the composition constituents, these limitations are held as non-critical and obviated by the prior art. Nyström provides the general combination of active agent particles with bio/mucoadhesive particles, along with suggestions to specific excipients. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having

various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With these aspects taken into consideration, one of ordinary skill in the art would have been motivated to combine the composition of Nyström along with its suggestions, with the knowledge in the art. A skilled practitioner would have been motivated by the suggestion of lubricants by Nyström, to combine the fentanyl and sodium lauryl sulfate of Stanley into the formulation of Nyström. A skilled artisan would have been aware of the therapeutic properties of OTFC, and been motivated to include it into the composition as well. One of ordinary skill in the art would have been motivated to combine the teachings of Stanley with those of Nyström in order to provide analgesic properties to the composition and to provide sufficient lubrication though the use of the sodium lauryl sulfate. A skilled artisan also would have followed the teachings of Fine to discover the sublingual and transmucosal properties of fentanyl. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine these teachings with an expected result of an ordered mixture that is essential free of water and capable of delivering fentanyl to a patient in need, relieving whatever disorder is present.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lewis et al (EP 0 144 243) discloses a composition for the sublingual delivery of analgesics comprising mannitol and other water-soluble excipients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MPY
September 20, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600